K 140093
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5. 510K Summary

MAR - 7 2014

Submitter	Anatomage Inc. 111 N. Market Street #800 San Jose, CA 95113 Phone: (408) 885-1474 Fax: (408) 295-9786
Regulatory Contact Person	Mike Mendez, Quality Manager Phone Number: (408) 885-1474 ext 119 Cell: (415) 370-9794
Device Name	Table
510(k) Preparation Date	January 07, 2014
Common Name	System, Image Processing, Radiological
Classification	Class II
Classification Name	Imaging Processing System, LLZ, 21 CFR 892.2050
Product Code	LLZ, 21 CFR 892.2050
Device Description	Table is a volumetric imaging software designed specifically for clinicians, doctors, physicians, and other qualified medical professionals. The software runs in Windows operating systems and visualizes medical imaging data on the computer screen. Users are able to examine anatomy on a computer screen and use software tools to move and manipulate images by turning, zooming, flipping, adjusting contrast and brightness, cutting, and slicing using either touch control or a mouse. The software also has the ability to perform measurements of angle and length. There are multiple tools to annotate and otherwise mark areas of interest on the images. Additionally, Table has the ability to demonstrate pathology examples of patient data for educational purposes.
Intended Use	Table is a software application used for the display and 3D visualization of medical image files from scanning devices such as CT and MRI. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, and assist in diagnosis, utilizing standard PC hardware.

	This device is not indicated for mammography use.
Equivalent Devices	K123519 Anatomage, InVivoDental
Technological Characteristic	Table and the predicate device are standalone software. These software devices are designed to be installed on standard off-the-shelf x86 processor based computers running the Windows operating system. DICOM data from medical imaging devices are visualized as volume or 2D images. A difference between Table and the predicate software is the touch interface that has been designed to complement a standard interface of mouse and keyboard. This interface is designed to provide a convenient way of using the software but does not change the functionality of the device from a system designed for keyboard and mouse controlled only. Also, the Table is designed to run on 64 bit operating systems only while InVivoDental is able to run on both 64 and 32 bit. While InVivoDental can perform volume and area measurements, Table performs the essential linear and angular measurement only. InVivoDental is designed with specialized tools for dental implant planning. Table does not have this feature. InVivoDental has tools for looking at custom cross-sectional troughs. This dental feature is not included in Table. Table cannot superimpose images nor perform cephalometric analysis. Table cannot save case workups, nor does it display imbedded patient information.
Non-Clinical Test Results	Testing confirmed that the software is stable and operating as designed. The following quality assurance measures were applied to the development of the system: · Risk Analysis · Requirements Reviews · Design Reviews · Performance testing (Verification) · Safety testing (Verification) · Final acceptance testing (Validation) · Bench testing to compare with predicate software Testing confirmed that the software is stable and operating as designed. Testing also confirmed that the software has been evaluated for hazards and that risk has been reduced to acceptable levels. Bench testing of the software with predicate software was performed by evaluation of images rendered by Table and

predicate software. This testing and evaluation included testing of measurement tools in both predicate and subject software and was evaluated by an expert in the field of radiology. This testing confirms that Table is as effective as its predicates in its ability to perform its essential functions of measurement and rendering of DICOM data.

Summary

Based on the intended use, product, performance, and testing information provided in this notification, the subject device has been shown to be substantially equivalent in technology, functionality, and indicated use to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Anatomage, Inc.
% Mr. Mike Mendez
Quality Manager
111 N. Market Street #800
SAN JOSE CA 95113

Re: K140093
Trade/Device Name: Table
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 7, 2014
Received: January 14, 2014

Dear Mr. Mendez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications For Use Statement

510(k) Number (if known): K140093

Device Name: Table

Indications for Use:

Table is a software application used for the display and 3D visualization of medical image files from scanning devices such as CT and MRI. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, and assist in diagnosis, utilizing standard PC hardware.

This device is not indicated for mammography use.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)
Evaluation and Safety
510(k) K140093